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09/600,932	09/08/2000	Nobutaka Wakamiya	19036/36615	2688

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EXAMINER
MITRA, RITA

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/600,932	WAKAMIYA, NOBUTAKA	
	Examiner	Art Unit	
	Christopher S. F. Low	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3, 4, 7, and 10 are canceled and 1, 2, 5, 6, 8, 9, and 11-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,8,9 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Papers filed

- The amendment/response filed 20 Mar 2003 has been entered. Claims 3, 4, 7, and 10 have been canceled as requested; claims 1, 3, 5, and 8 have been amended; and new claims 12 and 13 added.
- The supplemental information disclosure statement filed 19 Feb 2003 has been received and considered. A copy of the PTO 1449 is attached.
- The information disclosure statements referred to at page 8, item V have been rereviewed and appropriately considered. A copy of the documents is attached.

Restriction

To clarify the record, restriction to one of the following inventions should have been required under 35 U.S.C. 121 as follows:

I. Claims 1, 5, 6, 12, and 13 drawn to a polynucleotide encoding collectin and method of obtaining same are, for example, classified in Class 536, subclass 23.1 and Class 435 subclass 91.1.

II. Claims 8, 10, and 11, drawn to a collecting protein are for example classified in Class 530, subclass 350.

The products are patentably distinct and/or independent one from the other because

- each has different physical, chemical, and biological properties and function(s). Neither one can be substituted for the other. The search of Group I is not coextensive for that of Group II;
- based upon the claims, Hoppe *et al.* disclose that the protein (claim 11 which is part of Group II) was known (especially where there are one or more of a number of deletions, substitutions, and/or additions). Thus, there is a demonstration that the special technical feature was known in the art prior to the time the claimed invention was made; and,
- based upon the claims, Hoppe *et al.* disclose that the protein (claim 5 which is part of Group I) was known (especially where there is no apparent criticality placed on the hybridization conditions - page 6 of the instant specification indicates "... several modifications/alterations of these conditions may be made, based on the knowledge of the skilled art[isan] such as the concentration of the solution, incubation temperature and time"). Thus, there is a demonstration that the special technical feature was known in the art prior to the time the claimed invention was made

In view of the foregoing, unity of invention is lacking for a multiplicity of reasons, which makes the comments in the response unpersuasive.

The Office Action mailed 3 Oct 2002 indicated, however, that the restriction was made without traverse. It is further noted that the response filed 20 Mar 2003 indicates (page 7, item II)

the restriction was made with traverse. It is also noted that the 20 Mar 2003 response provides (paragraph item III bridging pages 7-8) a traverse.

Applicant's election of Group I with traverse in Paper No. 13 filed 20 March 2003 is acknowledged. The traversal is on the ground(s) that there was no holding of lack of unity in PCT/JP99/02238 is not found persuasive since the applications and claims are reviewed anew in the national stage filing. The additional commentary at page 8 is, however, persuasive because the first action on the merits contained examination of claims that should have been directed to Group II as put forth in the prior Office Action.

Insofar as claims to both groups of inventions were examined, the claims are rejoined and the requirement for restriction and/or holding of lack of unity is vacated.

In view of the above, claims 1, 2, 5, 6, 8, 9, and 11-13 are pending. The following grounds of objection and/or rejection are applicable to the pending claims. Objections and/or rejections not explicitly recited below are to be considered as withdrawn.

Informalities

The application should be reviewed for errors. The following is a sample of the informalities found. The application is stated to be a national stage filing but lacks the appropriate comment at page 1, first paragraph of the present specification as to the claim for priority. Language such as "This application is the national stage application of PCT/JP ... " is missing. Correction is required to perfect priority. Please note the previous objection to the specification and claim for priority. If applicant would not want the claim for priority, then as presently amended, there is no claim for priority.

The following error "lasbeling" appears at page 16, line 27. Correction is required.

Rejection(s) - 35 USC 101 product of nature

35 U.S.C. 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 9 and 11 are rejected under 35 USC101 as directed to nonstatutory subject matter. Claim 9 reads "A collection protein comprising ..." which is not differentiable from the protein as it exists in nature. See "isolated and purified" which may be inserted into the claim. Claim 11 is also rejected as dependent from claim 9 and for which, as dependent upon claim 9, is a product of nature for the reasons applicable to claim 9.

The comments (item VII, page 9) in the response file 20 Mar 2003 have been considered but are unpersuasive as to these two claims for the reasons indicated in the stated rejection as the above two claims do not have the isolated nor the purified language.

Rejection(s) - 35 USC 112 first paragraph enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention. Claim 12 is directed to obtaining a polynucleotide that encodes a collectin. The claim requires using the coding strand as a probe and hybridizing the probe (i.e., the coding strand) to a sample and isolating the hybridized polynucleotide. The probe (i.e., the template which is SEQ ID NO:1) is the coding strand. All that one would have obtained from this process as currently claimed are:

- a complement strand because that is what would have been expected to have hybridized to the coding strand;
- some but not all of the template because some would have been expected to have become degraded in the hybridization process; and,
- complement strands equivalent to the number of coding strands used in the probe (i.e., the coding strand) where there would, absent indication in the claim, have been no amplification of coding strands which have a sequence of SEQ ID NO: 1.

It is necessary to have started with the complement to the coding strand (SEQ ID NO:1) to have obtained the polynucleotide that encoded collectin. This is unstated in the claim. The claimed process uses the coding strand instead. The complement to the coding strand does not encode the same protein. For example, 5' ATG 3' which encodes Met, has a complement which is 3' CAT 5' (rewritten in 5' to 3' is 5' TAC 3') and encodes the amino acid Tyr. The claim is not technically accurate and is not enabled as currently presented.

The comments (pages 9-11) in the response filed 20 Mar 2003 have been considered but are unpersuasive as to new claim 12 for the reasons indicated in the stated rejection.

Rejection(s) - 35 USC 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 5 and 11 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reasons are as follows:

- Claim 5 is indefinite because the sequence of bases even where they hybridize to the noncoding complementary strand and as a sequence that encodes a protein with antiviral function, a Ca^{+2} carbohydrate recognition domain, a neck region, a collagen like region, and an N-terminal cysteine only define the function but not the sequence of the polynucleotide that was claimed by a structure. Where claim 5 recites SEQ ID NO: 1, the size of the noncoding complementary strand is undefined The claim should indicate the SEQ ID NO of the encoded protein as well. The blocking agent recited in line 5 does not appear to be defined as to what is the agent in the claim nor in the specification and the present response from applicant does not point to any particular pages and lines of the specification that define the blocking agent.

- Claim 11 is rejected for the same reasons applied to claim 5. In addition, claim 11 is indefinite because
  - in claim 8, the protein is defined by a specific sequence (SEQ ID NO:2); and,
  - in claim 9 by a specific polynucleotide (SEQ ID NO:1) that can encode only one specific polypeptide.

  Neither of the above claim 8 nor claim 9 permit variation of deletion, substitution, and/or addition of one or more amino acids in the collectin protein. Claim 11 is unclear as to how deletions, substitutions, and/or additions which are not permissible from the language of current claims 8 and 9 from which claim 11 depends is narrowed by expanding the limits of claims 8 and 9 by the language of claim 11.

The comments (page 11) in the response filed 20 Mar 2003 have been considered but are unpersuasive for the reasons indicated in the stated rejection. In addition, it would appear that claims 8 and 9 would more appropriately depend from claim 11. Given the ambiguity in the claims, the art rejections indicated below also appear appropriate.

Statutes for 35 USC 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability

under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Rejection(s) - 35 USC 102(b)

Claims 8, 9, and 11 all directed to proteins (where claims 8 and 9 include any one or more deletions, substitutions, and/or additions, then the following grounds of rejection are applicable to claims 8, 9, and 11 based on the interpretation that claim 11 is properly dependent and therefore, claims 8 and 9 do include deletions, substitutions, and/or additions) are rejected under 35 U.S.C. 102(b) as being anticipated by Hoppe *et al.* (1994) Protein Science 3: 1143-1158 which is one of a number of references disclosing a collectin protein.

The Hoppe *et al.* reference disclosed collectins which, absent factual evidence to the contrary, are anticipatory of claims 8, 9, and 11 because they contain any one or more deletions, substitutions, and/or additions. See at least the abstract and figures 1A, and 2 and the interpretation of these claims on the basis of language in claim 11 and that such language must be used in interpretation of claims 8 and 9 for claim 11 to be properly dependent upon claims 8 and 9. see also pages 1144+ which discuss the domain lectin, α-helical bundle, collagenous, N-terminal domains of the protein, carbohydrate binding (page 1149 as well as page 1145 as to Ca^{+2} dependent binding), and which bind to bacteria and viruses (pages 1150-1151).

Even where claims 8 and 9 recite a sequence, when the claims include via comprises and the deletion, substitution, and/or addition language, the actual sequence is not defined and therefore, the polypeptide can have any sequence such as would have been the polypeptide described in the Hoppe *et al.* reference.

Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession Number AB002631. While the reference would appear to be 24 Jan 1999, the record indicates a submission on 4 Apr 1997 which, absent factual evidence to the contrary, predates the instant application filing date and the foreign priority date. The reference discloses a polynucleotide that encodes a protein of SEQ ID NO:2 and is, absent factual evidence to the contrary, a polynucleotide with the sequence of SEQ ID NO:1. Thus, claims 1, 2, and 6 are anticipated. See the copy of the record and the alignment.

Claims 5 and 13 each directed to a polynucleotide are rejected under 35 U.S.C. 102(b) as being anticipated or, in the alternative as being obvious over Hoppe *et al.* (1994) Protein Science 3: 1143-1158.

Claim 5 recites various hybridization conditions in order to obtain a polynucleotide that hybridizes to the noncoding complement of SEQ ID NO:1 (T=55 °C; 5XSSC, 1% blocking agent; 0.1% lauryl sarcosine; 0.02% SDS; and washing at T=55 °C in 2XSSC). The nucleotide obtained is supposed to encode a protein with antiviral activity, have a Ca^{+2} dependent carbohydrate recognition domain, a neck region, a collagen-like region, and an N-terminal region containing a cysteine.

The Hoppe *et al.* reference disclosed "collectins have been characterized at the cDNA and the genomic levels and the sequences, and intron/exon positions, are consistent with the domain organization outlined in figure 1" which, absent factual evidence to the contrary, are anticipatory of claims 5 and 13 because claim 5 contains no sequence recitation of the result of the hybridization parameters. The recitation of SEQ ID NO:1 is the template used and is not *per se* the claimed polynucleotide. The claimed poly nucleotide may also contain any one or more deletions, substitutions, and/or additions of codons. Hoppe *et al.* disclose at pages 1144+ which discuss the domain lectin, α-helical bundle, collagenous, N-terminal domains of the protein, carbohydrate binding (page 1149 as well as page 1145 as to Ca^{+2} dependent binding), and which bind to bacteria and viruses (pages 1150-1151). Insofar that the protein is described in the reference to have these functions, it is anticipatory, if not obvious, that a cDNA or a genomic DNA (pages 1144, 1153-1154) would have had codons in the appropriate order that encoded these functions when transcribed and translated into a protein. The DNA is stated (page 1154) to be on the long arm of chromosome 10. Thus, where claim 5 and 13 do not specifically recite a sequence for the claimed polynucleotide, the reference would have resulted in a polynucleotide that encoded all of the characteristics polypeptide. Claim 13 would have been anticipated if not obvious since the coding strand would have been obtained, the complement is also defined and anticipated if not obvious.

In regard to hybridization parameters recited in claim 5, the parameters are not tied to obtaining a specific polynucleotide sequence defined by SEQ ID NO:, thus, any sequence obtained by the teachings in the Hoppe *et al.* reference would have been anticipatory if not obvious especially where specification pages 6 and 10-11 point to no criticality of the recited hybridization conditions of Temperature (T) = 55 °C; 5XSSC, 1% blocking agent; 0.1% lauryl sarcosine; 0.02% SDS; and washing at T=55 °C in 2XSSC. Of note is that these claims do not require the claimed polynucleotide to have had the same/identical sequence as SEQ ID NO: 1 and thus, the recitation of SEQ ID NO:1 in the claim as the template has no weight without recitation of the polynucleotide that is claimed has the specific SEQ ID NO:1.

Claims 5, 12, and 13 directed to a polynucleotide and method of obtaining same are rejected under 35 U.S.C. 102(b) as being anticipated or, in the alternative as being obvious over Kawai *et al.* (1997) Gene 186: 161-165 (PTO 1449, reference C6).

Kawai *et al.* disclose obtaining a DNA (page 162, right column) encoding a mannan binding protein (i.e., a collectin, page 161, introduction). The prehybridization temperature T is 68°C in 5XSSC, uses 1% blocking agent, contains 0.1% lauryl sarcosine, 0.02% SDS, hybridization at 60°C (meets claim criteria of 55°C), and washing in 2XSSC. Absent factual evidence to the contrary, the DNA obtained would have hybridized to a noncoding strand defined as the complement of SEQ ID NO:1. Thus, claim 5 is anticipated since the claim does not *per se* require the polynucleotide obtained to must have the sequence of SEQ ID NO:1 but only that it had hybridized under the recited conditions. The recited conditions are found in the Kawai *et al.* reference. In addition, the Kawai *et al.* reference indicates that the protein would have had an N-terminal cysteine rich domain, a collagen-like domain, a neck domain, a carbohydrate recognition domain (page 161) that absent factual evidence to the contrary would have been Ca^{+2} dependent and which protein inhibited virus activity (page 162, left column). Thus, claim 5 and 13 are anticipated if not obvious as the DNA obtained would have had the characteristics recited in the claims and have been obtained via the same method steps. Of note is that these claims do not require the claimed polynucleotide to have had the same/identical sequence as SEQ ID NO: 1 and thus, the recitation of SEQ ID NO:1 in the claim as the template has no weight without recitation of the polynucleotide that is claimed has the specific SEQ ID NO:1. Of note is that these claims do not require the claimed polynucleotide to have had the same/identical sequence as SEQ ID NO: 1 and thus, the recitation of SEQ ID NO:1 in the claim as the template has no weight without recitation of the polynucleotide that is claimed has the specific SEQ ID NO:1.

The comments in the response filed 20 Mar 2003 have been considered but are unpersuasive as to the above stated grounds of rejection. Appropriate amendment to the claims would obviate the rejections.

Rejection(s) 35 U.S.C. 103

Claims 1, 2, 5, 6, 8, 9, and 11-13 are rejected under 35 U.S.C. 103 as being obvious over Kawai *et al.* (1997) Gene 186: 161-165 (PTO 1449, reference C6) taken with GenBank Accession Number AB002631.

Kawai *et al.* disclose obtaining a DNA (page 162, right column) encoding a mannan binding protein (i.e., a collectin, page 161, introduction). The prehybridization temperature T is 68°C in 5XSSC, uses 1% blocking agent, contains 0.1% lauryl sarcosine, 0.02% SDS, hybridization at 60°C (meets claim criteria of 55°C), and washing in 2XSSC. Absent factual evidence to the contrary, the DNA obtained would have hybridized to a noncoding strand defined as the complement of SEQ ID NO:1. The recited conditions are found in the Kawai *et al.* reference. In addition, the Kawai *et al.* reference indicates that the protein would have had an N-terminal cysteine rich domain, a collagen-like domain, a neck domain, a carbohydrate recognition domain (page 161) that absent factual evidence to the contrary would have been Ca^{+2} dependent and which protein inhibited virus activity (page 162, left column). Thus, claim 5 and 13 are anticipated if not obvious as the DNA obtained would have had the characteristics recited in the claims and have been obtained via the same method steps. Of note is that these claims do not require the claimed polynucleotide to have

had the same/identical sequence as SEQ ID NO: 1 and thus, the recitation of SEQ ID NO:1 in the claim as the template has no weight without recitation of the polynucleotide that is claimed has the specific SEQ ID NO:1.

Kawai *et al.* provide motivation of obtain additional collectins/related proteins. Kawai *et al.* point to activation of complement (page 162, left column) and mediation of immunity via these proteins. The function of collectins alone would also have motivated one of skill in the art to have used the teachings in either of the Hoppe *et al.* or the Kawai *et al.* reference and to have modified same by using the polynucleotide described in GenBank Accession Number AB002631 or the complement thereof in place of the genetic material disclosed in the Kawai et al. reference since the polynucleotide encoded a collectin.

Thus, one of ordinary skill in the art would have had the claimed polynucleotide encoding the polypeptide with the claimed features and isolated by the process recited in the claims; the claimed polypeptide with the claimed features, and the process of obtaining the polynucleotide. The combined disclosures make the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

No claims are allowed.

Relevant Art

The Ohtani *et al.* (1999) J. Biol. Chem. 274(19) 13681-13689 reference disclosed the complete invention but is not art on the basis of publication after applicant's effective filing date.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Christopher Low can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette 1096 OG 30 (15 Nov 1989). The Fax Center Number is (703) 872-9306.

Inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CSFL
23 Jun 2003

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